

Application No. 09/871,823  
Amendment dated: March 15, 2004  
Reply to Office Action dated October 16, 2003

### Remarks/Arguments

Applicant has amended Claims 1, 7-9, 10, 12, 13 and 15-24. New claims 28-42 have been introduced. Claims 1-42 are now in the application. Applicant submits that the independent claims remaining in the application read on all species disclosed, and thus are generic.

The Examiner rejected claims 7 and 8 for lack of antecedent for the term "the metal foil". Applicant has amended claims 7 and 8 to depend from claim 2 wherein the term "a metal foil" is first introduced.

The Examiner rejected claims 10 and 12-25 as being indefinite since dependent from a claim directed to unrelated subject matter. Applicant has changed the dependencies of these claims directed to diagnostic devices to depend from claim 9 defining the generic diagnostic device of the invention.

The Examiner rejected claim 12 for lack of antecedent for the term "the housing". Applicant amended claim 12 to depend from claim 9 wherein the term "a housing" is first introduced.

The Examiner rejected claim 13 for lack of antecedent for the terms "the opening" and "the module cavity". Applicant amended claim 13 to depend from claim 12. The term "a module cavity" is first introduced in claim 12 and the term "an opening" is first introduced in claim 10 from which claim 12 depends.

The Examiner rejected claims 21 and 22 as being redundant, since claim 8 from which they depended is directed to the same subject matter. Applicant has amended claims 21 and 22 to depend from claim 9 directed to a diagnostic device. Claim 8 is dependent from claim 1 which is directed to an electrode module. Thus, claims 21 and 22 are no longer redundant.

Applicant has introduced new claims 28-42. Claim 28 is dependent from claim 1. Claim 29 is a combination of the subject matter of original claim 6 and the limitations of the original base

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claim. Each of new claims 30-42 is dependent, either directly or indirectly from new claim 29. Thus, Applicant submits that no new search is required for the subject matter claimed in the new claims 28-42.

Claim 28 defines a combination of the electrode module of claim 1 with a housing, whereby the module is sealingly mounted to the housing to prevent sample fluid contact with the conductor elements while exposing the conductor elements to an exterior of the housing. This represents the subject matter of original claim 15 and the base claim, which matter was identified allowable by the Examiner.

The subject matter of Claim 29 is a combination of original claims 1 and 6, the combined subject matter of which was identified allowable by the Examiner.

Claims 30-33 are all dependent from claim 29. Claim 30 requires that the metal layer be a metal foil and the insulating layer an insulator foil. Claim 31 requires the carrier module be a chip carrier conforming to ISO Standard 7816. Claim 32 requires that the insulating layer include a perforation for each conductor element. The subject matter of these claims is fully supported by the specification as filed, since based on original claims 2-4 in combination with the subject matter of original claim 6.

Claim 33 is directed to a diagnostic device including the module of claim 29 mounted to a housing to expose the conductor elements to an exterior of the housing, which housing includes means to expose the membrane element to a sample fluid. Claim 33 is directed to a combination of original claims 6, 9 and 15 (in part) and is thus fully supported by the specification as filed.

Claims 34-42 are all dependent from claim 33. Claims 34-40 include the subject matter of claim 33 and original claims 11-17 respectively. Claim 41 is directed to a combination of claim 33 with the subject matter of original claim 19, and Claim 42 is a combination of claim 33 with the subject matter of original claim 24. Thus, all of claims 34-42 are fully supported by the specification as filed.

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The examiner has rejected claims 1, 2, 4, 9 and 11 of the application as filed as being anticipated by USP 5,628,890 to Carter et al. From a study of its figures and description, it is apparent that the Carter et al. reference teaches an electrode strip including a substrate layer (1), a metal layer on the substrate layer and divided into at least two metal conductor elements (4, 5, 5a), and an insulating layer (7) on the conductor elements. Three electrodes are formed on the electrode strip and a membrane element (9) imparts chemical sensitivity to the electrode. The membrane is applied to the insulating layer and in contact with the conductor elements through the insulating layer. Applicant submits that the claims as amended are patentable over the teachings of the Carter et al. reference and define an electrode module which is much less structurally complicated and thus much less expensive to manufacture.

Amended claim 1 defines the carrier module as "made of a laminate of an insulating layer having opposing first and second sides and a metal layer applied to the first side". The claim further requires that the membrane element be "applied to the second side of the carrier layer". The amended claim 1 further requires that the electrode module structure as claimed permit electrical contact and sample fluid contact on opposite sides of the electrode module. This is distinct from Carter et al. wherein, irrespective whether the substrate layer (1) or the insulating layer (7) is considered to represent the insulating layer of the electrode module as claimed, electrical and sample fluid contact on opposite sides of the insulating layer is not possible. When comparing the electrode strip structure of Carter et al. and the structure of the electrode module of the present invention, it is readily apparent that the Carter et al. electrode strip includes separate supporting and insulating layers (substrate layer 1 and insulating layer 7 respectively). This results in an electrode strip which is structurally much more complicated than the electrode module of the invention, wherein the insulating layer also functions as the substrate or carrier layer of the module. No separate substrate or carrier layer is included or necessary in the structure as defined in claim 1. This is distinct from the teachings of Carter et al. wherein the only insulating layer which could also function as a carrier layer for the electrode strip, the substrate layer (1), functions only as a base with all other layers of the electrode strip being stacked on one side of the base, thereby making electrical and sample fluid contact on opposing sides of the substrate layer (1) impossible. Thus, Applicant

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respectfully submits that the subject matter of amended claim 1 is not anticipated by the teachings of Carter et al.

Claims 2 and 4 are dependent from amended claim 1. Amended Claim 9 defines a diagnostic device including a housing and an electrode module as defined in amended claim 1 mounted to the housing to permit electrical contact and sample fluid contact on opposite sides of the carrier layer. Claim 11 is indirectly dependent from amended claim 9. Thus, amended claim 9 and claims 2, 4, and 11 all recite the features discussed above which distinguish the electrode module of the invention from Carter et al. Applicant respectfully requests that the rejection of claims 1, 2, 4, 9 and 11 under 35 USC 102(b) be withdrawn.

It is readily apparent from a comparison of the differences in structure between the electrode module of the invention and the electrode strip disclosed in Carter et al. that the electrode module of the present invention is structurally much simplified and requires fewer structural components and manufacturing steps than the electrode strip of Carter et al., making the electrode module of the invention much less expensive to manufacture. This is achieved by combining the functions of both a supporting substrate layer and an insulating layer into the single insulating layer of the electrode module of the invention. This not only reduces the cost of the materials used in the production of the electrode module, but reduces manufacturing cost and time, all of which combines to a significant economic advantage not apparent from the cited art, which economic advantage is important for unit use devices such as the blood test strip of Carter et al. and even more important for low volume unit use applications where economies of scale cannot be achieved during manufacturing. Applicant submits that not only do Carter et al. not teach a functional electrode module including fewer components, but Carter et al. neither teach nor teach towards the possibility of simplifying the structure of their electrode strip by combining the functions of the substrate layer and the insulating layer into a single insulating layer. Nor do Carter et al. appreciate that such a simplified structure would result in an economic advantage. Applicant respectfully submits that by teaching an electrode module structure wherein all of the electrode components are successively stacked onto the same side of a base layer, Carter et al. teach away from the possibility of building a self supporting electrode module which does not require a separate, underlying electrode support.

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It is also apparent from a comparison of the electrode strip of Carter et al. with the electrode module of the present invention that the structure required for external electrical contact with the respective electrodes is much simplified in the electrode module of the invention. The stacking of all layers of the electrode strip onto the electrode support in Carter et al. results in the conductor portions (4, 5, 5a) of the electrodes being sandwiched between the base layer and the insulating layer. To overcome this problem, Carter et al. teach the formation of lead conductors 2 connecting the conductor portions (4, 5, 5a) to the externally accessible electrical contacts 3. In contrast, in the electrode module of amended claim 1 direct external electrical contact to the conductor elements is made possible by placing the conductor elements on the back of the insulating and carrier layer while the membrane element of the electrode for exposure to the sample fluid is positioned on the side of the insulating layer opposite the conductor elements. As such, Applicant submits that claim 1 is neither anticipated nor obvious in view of Carter et al. Applicant further submits that as claims 2, 4, 9 and 11 either include the subject matter of claim 1 or are directly or indirectly dependent therefrom they can also not be rendered anticipated or obvious by Carter et al.

Further, as claims 3, 5, 7 and 8 are all depend from claim 1, either directly or indirectly, they are thus narrower in scope than the independent claim. As such, Applicant submits that claims 3, 5, 7 and 8 are patentable over Carter et al., Rankl et al., Winarta et al. and Holker et al. whether taken alone or in combination.

Rankl et al teach the use of a chip carrier module as the carrier for an integrated circuit chip. Thus, Rankl et al at best teach or teach towards the use of a carrier module as the carrier for a micro-fabricated semiconductor chip based electrode or separation device of the art, but not the use of the carrier module as an integral part within a structurally simplified electrode module in accordance with the present invention. Winarta et al. teach a structure principally equal to the one disclosed in Carter et al., wherein all conductive, insulating and electrode layers are stacked on top of an additional, separate substrate layer (20) and electrical and sample fluid contact is made on the same side of the substrate layer. Winarta et al. neither teach nor teach towards a simplified structure including a single insulating layer functioning both as carrier for the overall structure and as insulator separating the electrically contacting

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part of the electrode from the membrane element for contact with the sample fluid. Holker et al. teach a method of making a sensor by stacking successive metal layers onto a supporting substrate. Again, no teaching of or teaching towards a structure as defined in claim 1 is found in Holker et al. , since all sensors disclosed include the additional, insulating base layer onto which all remaining layers are stacked. As such, Applicant requests withdrawal of the rejection of claims 3, 5, 7 and 8 under 35 USC 103(a).

Amended Claim 9 is directed to a diagnostic device including a housing and an electrode module mounted to the housing. The electrode module is as defined in claim 1. Thus, the arguments presented above in relation to Carter et al. also apply to this claim. Furthermore, the above arguments presented with respect to the cited references of Rankl et al., Winarta et al. and Holker et al. also apply to this claim. In addition, since claims 10-12, 14, 16-19 and 20-25 listed above are all depend from amended claim 9, either directly or indirectly, they are thus submitted to be more narrow in scope than the independent claim. Furthermore, since amended claim 9 includes all the features of amended claim 1 as well as the additional limitations of a housing and the mounting of the electrode module to the housing for external exposure of the conductor elements, amended claim 9 is submitted to be more limited in scope than amended claim 1. Therefore, in view of the arguments presented above, Applicant submits that claims 10-12, 14, 16-19 and 20-25 listed above are patentable over Carter et al. in view of Rankl et al., Winarta et al. and Holker et al.

Lauks et al. and Douglas et al. teach disposable sensing devices and electrochemical test devices including structurally complicated devices all of which include a substrate or carrier layer onto which multiple additional layers are stacked. Neither reference teaches or teaches towards the much simplified and much more economically manufactured diagnostic device of amended claim 9. Thus, Applicant respectfully submits that the diagnostic devices of amended claim 9 and claims 10-12, 14, 16-19 and 20-25 listed above are not rendered obvious by the teachings of Carter et al., Rankl et al., Winarta et al., Holker et al., Lauks et al. and Douglas et al. when taken alone or in combination and requests withdrawal of the rejection of those claims under 35 USC 103(a).

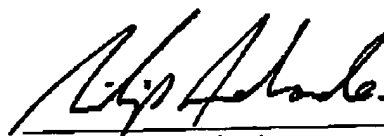
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New claims have been added and there are presently 4 independent claims and 42 claims in total pending in the application. Thus, 1 independent claim and 15 dependent claims were added. The Commissioner is authorized to charge the requisite fees (1X\$43 and 15X\$9) in the amount of \$178.00 to our firm's deposit account # 501593.

As the first deadline for response to the October 16, 2003 Office Action on the present application expired on January 16, 2004, a two month extension is requested and the Commissioner is authorized to charge the requisite fee in the amount of \$420.00 to our firm's deposit account # 501593.

Applicant submits that the application is now in condition for allowance and earnestly solicits action to that end.

Respectfully submitted,  
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